U.S. Food and Drug Administration
Department of Health and Human Services

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FDA Announces Rapid Response Team to Combat Pandemic (Avian) Flu

Team Will Boost Agency's Efforts to Expedite Manufacturing of Tamiflu and New Drugs to Treat Avian Flu

In response to the emerging threat of pandemic (Avian) influenza, the Food and Drug Administration (FDA) today announced the formation of a Rapid Response Team to ensure that antiviral drugs are available to the American people, in the event they are needed. While there is no current flu pandemic, the team will help ensure an adequate supply of treatments, such as oseltamivir phosphate (Tamiflu) and other anti-influenza drugs, for stockpiling in the event there is an outbreak in the United States.

"Making sure Americans are protected against an outbreak of Avian flu is one of FDA's top priorities," said Andrew von Eschenbach, MD, Acting FDA Commissioner. "Using the Rapid Response Team approach, we believe we could review a complete drug application in six to eight weeks. Americans can be certain that FDA has the best scientific minds working together to ensure we have enough Tamiflu and other medications and to quickly get it to doctors and patients, if ever necessary."

In partnership with the Department of Health and Human Services, Centers for Disease Control and Prevention, National Institutes of Health, and industry, the Rapid Response Team will work to ensure every necessary measure is taken to provide an adequate and timely supply of antiviral drugs to treat Avian flu, if it should emerge in the United States.

The Rapid Response Team will address roadblocks to increased manufacturing of products, such as Tamiflu (oseltamivir phosphate). It is anticipated that Tamiflu production can be in full gear within 12 months, with substantial product available, should it be needed.

Partnering with industry, academia and other government agencies, the team will support the design and conduct of clinical studies to test new potential treatments for Avian influenza. In the event of a pandemic, such new medications could be made available under Emergency Use Authorization.

In addition, the team will facilitate the development and availability of safe and effective vaccines that could help protect Americans against a future pandemic, including from Avian flu. These efforts include measures to help increase vaccine manufacturing capacity and production of currently licensed vaccines using Avian flu strains, and facilitating and evaluating studies that use new technologies.

As the threat of pandemic flu emerges as a public health threat, FDA anticipates an increase in the sale of counterfeit or fraudulent treatments. Presently, the agency is not aware of any counterfeit Tamiflu cases in the United States, however, there are initiatives in place to deter counterfeiters and parties who sell fraudulent or phony products to treat or prevent Avian flu.

FDA will continue to work with stakeholders in the U.S. drug distribution system to strengthen the safety and security of the domestic drug supply and will continue to:

- Actively monitor internet sites and will partner with internet service providers to identify and stop fraudulent activity.
- Aggressively seek out and prosecute those who seek to prey on innocent people in a time of crisis.
- Encourage pharmaceutical manufacturers to take advantage of new technologies that provide protective packaging and other features to ensure the product is both authentic and has not been tampered with.

The FDA Counterfeit Alert Network is ready and available to help disseminate information in the event of counterfeit incident. The Counterfeit Alert Network is a partnership between FDA and numerous organizations that have agreed to distribute FDA approved messages to their members about counterfeits on a timely basis to assure rapid action to minimize the risk of exposure to counterfeits. In the event of a confirmed counterfeit case in the U.S., FDA will send an Alert to these partners. FDA will send out an FYI notice to partners if a counterfeit incident is confirmed elsewhere in the world that could affect U.S. patients.

To minimize the risk of counterfeit or fraudulent flu treatments, the FDA recommends the following:

- Consumers should buy medicines only from U.S. state-licensed pharmacies.
- When buying medicines over the Internet, consumers should look for the National Association of Boards of Pharmacy VIPPS seal. This seal tells consumers that the web site has been certified, and if people want to buy a medicine on line, this is a legitimate pharmacy to purchase it from.
- Only use medicine that has been prescribed for you by your doctor and do not rely on websites that will provide you with a prescription for the medicine without a true doctor-patient relationship.

The agency will continue to collaborate with state and local health departments to educate consumers about the dangers of fraudulent treatments and preventions for Avian flu. For more information on seasonal and pandemic flu, check these web sites:

Pandemic Flu (HHS)
Pandemic Flu (CDC)
Seasonal Flu (NIAID)
Seasonal Flu (FDA
Report Unlawful Sales of Medical Products on the Internet (English)
(Spanish)
Buying Medicines and Medical Products Online
Combating Counterfeit Drugs

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